

REMARKS

Claims 1, 3, 5-6 and 14-17 are pending. Claim 2 has been canceled. Claim 1 was amended to more clearly claim what the Applicants consider to be their invention.

Claims 1 was amended to recite the group of amino acids from which Y may be selected. Support for amended Claim 1 can be found at least original Claim 2.

REJECTIONS UNDER 35 U.S.C. § 103

1. Claims 1, 3, 6, and 14-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Drmanac *et al.* (WO 01/75067) as evidenced by Alberts (*Molecular Biology of the Cell*, 3rd Ed., 1994, p. 57) in view of Arlinghaus *et al.* (U.S. Patent No. 6,107,457, issued on August 22, 2000). Applicants respectfully traverse this rejection to the extent that it applies to the claims as amended.

In making a determination of obviousness under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that (1) the prior art suggests the invention developed, and (2) the prior art indicates that the invention would have a reasonable likelihood of success. *See In re Dow Chem. Co.*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988); *In re Geiger*, 815 F.2d 686, 2 U.S.P.Q.2d 1276 (Fed. Cir. 1987). In order for a reference to be effective prior art under 35 U.S.C. § 103, it must provide a motivation whereby one of ordinary skill in the art would be led to do that which the applicant has done. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1535, 218 USPQ 871, 876 (Fed. Cir. 1983).

Drmanac *et al.* discloses the polypeptide of SEQ ID. NO: 44631. (Office Action, p. 3). The Office Action alleges that residues 68-71 have the sequence GARRAGGT_PPRAPR, and further alleges that this polypeptide is within the scope of Applicants' SEQ ID NO: 210. (Office Action, p. 3).

Applicants first note that claims 3, 6, and 14-16 depend from claim 1, and therefore, by definition, comprise all of the limitations of independent claim 1. Second, Applicants note that independent claim 1 has been amended. Amended claim 1 now recites a synthetic apolipoprotein-E mimicking polypeptide comprising an amino acid sequence X-Y-Arg-Arg-Y-Y-X-X-Y-Y-Arg-Y-Y-Arg (SEQ ID NO: 210), wherein X is glycine, threonine, serine or alanine, *wherein Y is selected from the group consisting of phenylalanine, tyrosine, leucine, isoleucine, valine, and tryptophan*, wherein the polypeptide comprises an acetyl group at the N-terminus and an amide group at the C-terminus, wherein the polypeptide is capable of forming an amphipathic α helical structure, and wherein the polypeptide is also capable of binding lipoproteins.

As amended, claim 1 now recites a synthetic apolipoprotein-E mimicking polypeptide comprising an amino acid sequence X-Y-Arg-Arg-Y-Y-X-X-Y-Y-Arg-Y-Y-Arg, wherein Y is selected from the group consisting phenylalanine, tyrosine, leucine, isoleucine, valine, and tryptophan. Applicants note that the amino acid *Proline is not a member of this group*. As described above, the polypeptide described by Drmanac *et al.* comprises at least three Proline residues within the sequence the Office Action alleges makes obvious the currently claimed synthetic apolipoprotein-E mimicking polypeptide. Applicants respectfully submit that Claim 1, as currently amended, does not comprise a Proline residue within the consensus sequence of SEQ ID NO: 210. Accordingly, Applicants submit that the Office Action's allegation that Drmanac *et al.* teaches a polypeptide, *i.e.*, SEQ ID NO: 44631, that is within the scope of Applicants' claimed SEQ ID NO: 210 is incorrect. In addition, Applicants submit that nowhere in Drmanac *et al.* is there any teaching, motivation or suggestion to alter SEQ ID. NO: 44631 as

disclosed in Drmanac *et al.* As such, Applicant's submit that Drmanac *et al.* fails to disclose or suggest the currently claimed synthetic apolipoprotein-E mimicking polypeptide.

The Office Action also cites Alberts (Molecular Biology of the Cell, 3rd Ed., 1994, p. 57) for providing evidence that G, A, and P are all non-polar, and thus hydrophobic residues. Applicants do not take issue with this statement, however Alberts fails to disclose or suggest a synthetic apolipoprotein-E mimicking polypeptide comprising an amino acid sequence X-Y-Arg-Arg-Y-Y-X-X-Y-Y-Arg-Y-Y-Arg, wherein Y is selected from the group consisting phenylalanine, tyrosine, leucine, isoleucine, valine, and tryptophan. The Office Action, as described above, relied on the basic polypeptide taught by Drmanac *et al.* as the basis for a core polypeptide, but as described above, Drmanac *et al.* fails to disclose or suggest the currently claimed synthetic apolipoprotein-E mimicking polypeptide. Alberts, which is cited for its teaching of nonpolar amino acids fails to supplement the elements missing from Drmanac *et al.*

Arlinghaus *et al.* which is cited for allegedly teaching that an acetyl or amide group can be added to the N-terminus and C-terminus of a protein, respectively also fails to supplement the elements missing from Drmanac *et al.* and Alberts. (Office Action, p. 4). Specifically, Arlinghaus *et al.* fails to disclose or suggest a synthetic apolipoprotein-E mimicking polypeptide comprising an amino acid sequence X-Y-Arg-Arg-Y-Y-X-X-Y-Y-Arg-Y-Y-Arg, wherein Y is selected from the group consisting phenylalanine, tyrosine, leucine, isoleucine, valine, and tryptophan. In fact, the Office Action admits that Arlinghaus *et al.* does not teach a protein within the scope of Applicants' SEQ ID NO: 210. (Office Action, p. 4).

As such, Drmanac *et al.*, Alberts, and Arlinghaus *et al.*, either alone or in combination, fail to teach or suggest each and every element of claims 1, 3, 6, and 14-16. Accordingly,

Drmanac *et al.*, Alberts, and Arlinghaus *et al.* do not make obvious claims 1, 3, 6, and 14-16. Applicants respectfully request withdrawal of this rejection.

DOUBLE PATENTING REJECTION

Claims 1-3, 5-6, and 14-17 are *provisionally* rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 14-17 of co-pending U.S. Patent Application No. 11/405,601. Applicants respectfully traverse this rejection.

Applicants submit with this Amendment a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) and is relative to U.S. Patent Application No. 11/405,601. It is believed that this Terminal Disclaimer obviates the present provisional obviousness-type double patenting rejection.

CONCLUSION

Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. If such contact may enhance the efficient prosecution of this application to issuance, then the Examiner is invited and encouraged to directly contact the undersigned.

No fee is believed due; however, the Commissioner is hereby authorized to charge to Deposit Account No. 14-0629 any additional fees that may be required, or to credit to the same account any overpayment of fees.

Respectfully submitted,

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